

April 18, 2006

To: House Agriculture Committee Members

From: Tonia Ritter, Legislative Counsel



Re: Senate Bill 777, Seed Bill

Today you have the opportunity to make a very important vote to support Michigan agriculture and the future of the bio-economy in Michigan. Michigan Farm Bureau strongly urges your support of Senate Bill 777.

Michigan Farm Bureau supports S.B. 777, as it retains seed regulation at the federal and state levels, where the regulatory expertise resides to understand and evaluate emerging technologies for agricultural use. At our state annual meeting this past December, our farmer members declared in policy: "We oppose all attempts by local political subdivisions to limit the production or use of genetically modified crops or animals."

This legislation supports all farmers rights to operate his/her farming operation in the best way he/she deems appropriate, by ensuring decisions regarding seed regulation in the state are made in a scientifically informed and uniform approach. As farming operations span from township to township, county to county, it would be increasingly difficult to monitor farming practices with a patchwork quilt of regulations regarding seed use that are not based in science.

This legislation does not remove the ability of individuals to work cooperatively together to ensure the opportunity for growing value-added crops, whether that is certified seed or organic agriculture. For years the certified seed industry has been working collectively, neighbor to neighbor and farmer to farmer to assure specific crops are not cross-pollinated through the use of various isolation practices.

Inspired by laws enacted around the country and throughout the Midwest, this legislation keeps Michigan agriculture competitive with other states, allowing for the use of advancing seed technologies that will grow the bio-economy of the state.

Michigan agriculture is thriving with diversity, and value added agriculture is growing every day; we're simply asking for the continuation of this environment for agriculture's growth in Michigan's economy. Michigan Farm Bureau strongly urges your support of S.B. 777.



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2002

August, The U.S. Department of Agriculture creates a new unit within the Animal and Plant Health Inspection Service called Biotechnology Regulatory Services (BRS) to focus on USDA's key role in regulating and facilitating biotechnology.

2001

APHIS' establishes Biotechnology Policy Group in Program Planning and Development to coordinate biotechnology policy

2001 Council on Environmental Quality (CEQ) of OSTP publishes Case Studies of Environmental Regulations for Biotechnology

2000

Plant Protection Act consolidates and extends USDA authority to regulate Plant Health – Title 7 Chapter 61, 104

1997

May 2, USDA changes eligibility requirements for field testing under Notification -- Simplification of Requirements and Procedures for Genetically Engineered Organisms 7 CFR 340

APHIS's dissolves BBEP, and transfers biotechnology functions to APHIS PPQ

1995

EPA registers first pest protected plant—Monsanto's New Leaf potato

1993

March 31, USDA publishes alternative requirements for field testing--Notification Procedures for the Introduction of Certain Regulated Articles 7CFR 340.3

March 31, USDA publishes rules to allow determinations that certain plants are no longer Regulated Articles-- Petition for Nonregulated Status 7CFR 340.

1992

May 29, FDA publishes its "Statement of Policy: Foods Derived from New Plant Varieties (57 FR 22984)

October 19, USDA APHIS deregulates a product for the first time, Calgene's FLAVR SAVR tomato

1988

First field test of a potential commercial product - Calgene plants Tobacco Mosaic Virus-resistant tomatoes

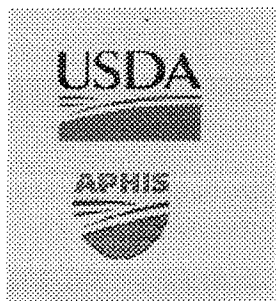
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October 1, USDA's establishes Biotechnology, Biologics and Environmental Protection (BBEP) to regulate biotechnology and other environmental programs

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**1987**

June 16, USDA publishes a rule for permitting field tests (7CFR 330 and 340) "Introduction of Genetically Engineered Organisms"

November 25, USDA under 7CFR 340.3 authorizes first field test -- Calgene's Bromoxynil-Resistant Tobacco

**1986**

May 30, USDA authorizes by means of an "Opinion Letter" the first release of genetically engineered organisms in the environment: Agracetus' crown-gall resistant tobacco.

June 26, Office of Science and Technology Policy (OSTP) publishes the "Coordinated Framework for Regulation of Biotechnology" that directs how existing laws and agencies including USDA, EPA and FDA should regulate biotechnology (51 *Federal Register* 23302)

**1985**

1985 January, Advanced Genetic Systems injects live genetically engineered "ice minus" bacteria into fruit trees in the open air on the roof of their building prefatory to filing an application for an EPA Experimental Use Permit (EUP) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

**1983**

NIH's Recombinant DNA Advisory Committee authorizes field tests of the genetically engineered "ice-minus" strains of *Pseudomonas syringae* and *Erwinia herbicola* 48 *Federal Register* 16459

**1978**

NIH's Recombinant DNA Advisory Committee implements Guidelines for Research with Genetically Engineered Organisms 43 *Federal Register* 60108

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## Biotechnology Regulatory Services

# United States Regulatory Oversight in Biotechnology Responsible Agencies - Overview

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The Agencies primarily responsible for regulating biotechnology in the United States are the US Department of Agriculture (USDA), Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). Products are regulated according to their intended use, with some products being regulated under more than one agency.

Agency	Products Regulated	Additional Info.
<a href="#">U.S. Department of Agriculture</a>	plant pests, plants, veterinary biologics	<a href="#">USDA Contacts</a> <a href="#">Laws, Regs., Rules</a>
<a href="#">Environmental Protection Agency</a>	microbial/plant pesticides, new uses of existing pesticides, novel microorganisms	<a href="#">EPA Contacts</a> <a href="#">Laws, Regs., Rules</a>
<a href="#">Food and Drug Administration</a>	food, feed, food additives, veterinary drugs, human drugs and medical devices	<a href="#">FDA Contacts</a> <a href="#">Laws, Regs., Rules</a>

Before commercialization, genetically engineered plants/organisms must conform with standards set by State and Federal marketing statutes such as State seed certification laws, the Federal Food, Drug, and Cosmetic Act (FFDCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Toxic Substances Control Act (TSCA), and the Federal Plant Pest Act. There are no national requirements for varietal registration of new crops.

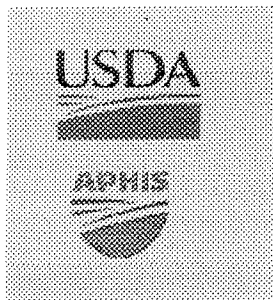
### EXAMPLES:

New Trait/Organism	Regulatory Review Conducted by:	Reviewed for:
Viral Resistance in food crop	USDA EPA FDA	Safe to grow Safe for the environment Safe to eat
Herbicide Tolerance	USDA EPA	Safe to grow New use of companion herbicide

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in food crop	FDA	Safe to eat
Herbicide Tolerance in ornamental crop	USDA EPA	Safe to grow New use of companion herbicide
Modified Oil content in food crop	USDA FDA	Safe to grow Safe to eat
Modified flower color ornamental crop	USDA	Safe to grow
Modified soil bacteria degrades pollutants	EPA	Safe for the environment

### Agency Information



**U.S. Department of Agriculture - USDA**

Within USDA, the Animal and Plant Health Inspection Service (APHIS) is responsible for protecting US agriculture from pests and diseases. Under the authority of the Federal Plant Pest Act, APHIS regulations provide procedures for obtaining a permit or for providing notification, prior to "introducing" a regulated article in the United States. Regulated articles are considered to be organisms and products altered or produced through genetic engineering that are plant pests of that there is reason to believe are plant pests. The act of introducing includes any movement into (import) or through (interstate) the United States, or release into the environment outside an area of physical confinement. The regulations also provide for a petition process for the determination of nonregulated status. Once a determination of nonregulated status has been made, the product (and its offspring) no longer requires APHIS review for movement or release in the US.

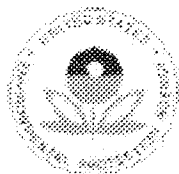
**FIELD TRIAL APPROVALS:** [Available at APHIS Cooperator Web site](#)

**PRODUCT APPROVALS:** [Available at APHIS Web site](#)

**CONTACTS:** [Biotechnology Staff](#)

Name	Title	Phone	Address
<a href="#">Dr. Neil Hoffman</a>	Director, Regulatory Division	301-734-6331	4700 River Rd Riverdale, MD 20737
<a href="#">Dr. John Turner</a>	Director, Policy Coordination Division	301-734-8365	4700 River Rd Riverdale, MD

20737



## Environmental Protection Agency - EPA

EPA ensures the safety of pesticides, both chemical and those that are produced biologically. The BioPesticides and Pollution Prevention Division of the Office of Pesticide Programs (OPP) uses the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to regulate the distribution, sale, use and testing of plants and microbes producing pesticidal substances. Under the Federal Food, Drug and Cosmetic Act (FFDCA) EPA sets tolerance limits for substances used as pesticides on and in food and feed, or establishes an exemption from the requirement of a tolerance.

EPA also establishes tolerances for residues of herbicides used on novel herbicide-tolerant crops.

Under the authority of the Toxic Substances Control Act (TSCA), EPA's TSCA Biotechnology Program regulates microorganisms intended for commercial use that contain or express new combinations of traits. This includes "intergeneric microorganisms" formed by deliberate combinations of genetic material from different taxonomic genera.

**FIELD TRIAL APPROVALS - PLANTS:** Available from Contacts listed below

**FIELD TRIAL APPROVALS - MICROBES:** Available at EPA-TSCA Web site

### PRODUCT APPROVALS AND TOLERANCE EXEMPTIONS

#### CONTACTS:

##### Office of Prevention, Pesticides and Toxic Substances Biotechnology Staff

Name	Title	Phone	Address
<u>Dr. Elizabeth Milewski</u>	Advisor	202-564-8492	1200 Pennsylvania Ave NW Washington DC 20260

##### Office of Pollution Prevention and Toxics TSCA Biotechnology Program (Microbial Products of Biotechnology)

Name	Title	Phone	Address
<u>David Giamporcaro</u>	Chief, Biotech. Rules Program	202-564-8127	1200 Pennsylvania Ave NW Washington, DC 20460

**BioPesticides and Pollution Prevention Division (BPPD)**  
**- Office of Pesticide Programs**

Name	Title	Phone	Address
<u>Dr. Janet L. Andersen</u>	Director, BPPD	703-308-8712	1200 Pennsylvania Ave NW Washington, DC 20460
<u>Dr. Phil Hutton</u>	Branch Chief, Microbial and Plant Pesticides	703-305-6098	1200 Pennsylvania Ave NW Washington, DC 20460
<u>Dr. William Schneider</u>	Biotech Notifications: Small Scale Field Testing	703-308-8683	1200 Pennsylvania Ave NW Washington, DC 20460



**Food and Drug Administration - FDA**

As a part of the Department of Health and Human Services, FDA regulates foods and feed derived from new plant varieties under the authority of the Federal Food, Drug, and Cosmetic Act. FDA policy is based on existing food law, and requires that genetically engineered foods meet the same rigorous safety standards as is required of all other foods. FDA's biotechnology policy treats substances intentionally added to food through genetic engineering as food additives if they are significantly different in structure, function, or amount than substances currently found in food. Many of the food crops currently being developed using biotechnology do not contain substances that are significantly different from those already in the diet and thus do not require pre-market approval. Consistent with its 1992 policy, FDA expects developers to consult with the agency on safety and regulatory questions.

**FINAL CONSULTATIONS:** [Available at FDA Web site](#)

**CONTACTS:** [Center for Food Safety and Applied Nutrition \(CFSAN\)](#)

Name	Title	Phone	Address
<u>Dr. James Maryanski</u>	Biotechnology Strategic Manager	301-436-1715	5100 Paint Branch Pkwy College Park, MD 20740
<u>Dr. Eric Flamm</u>	Microbiologist	202-418-3053	5600 Fishers Lane Rockville, MD 20857

**Joint United States Federal Agencies Unified Website**

For a list of Decision documents for all Federal Agencies:



- [United States Regulatory Agencies Unified Biotechnology Website](#)
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## Relevant Laws - Regulations - Rules

### USDA

#### LAWS

- [Federal Plant Pest Act](#) - 7 USC 7B

#### REGULATIONS

- [7 CFR 340 \(pdf version\)](#) - Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests
  - [Simplification of Requirements and Procedures for Genetically Engineered Organisms and Products](#)  
Federal Register: May 2, 1997 (Volume 62, Number 85)
  - [Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status](#)  
Federal Register: March 31, 1993 (Volume 58, Number 60)
  - [Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests](#)  
Federal Register: June 16, 1987 (Volume 52, Number 115)
- 

### EPA

#### LAWS

- [Federal Insecticide, Fungicide, and Rodenticide Act \(FIFRA\)](#) - 7 USC 136
- [Federal Food, Drug, and Cosmetic Act \(FFDCA\)](#) - 21 USC 9
- [Toxic Substances Control Act \(TSCA\)](#) - 15 USC 53

#### REGULATIONS

##### Regulations under FIFRA/FFDCA

40 CFR Parts 152, 172, 174, 180

- [Plant-Pesticides, Supplemental Notice; Proposed Rule](#)  
Federal Register: May 16, 1997 (Volume 62, Number 95)
- [Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act; Proposed Rule](#)  
Federal Register: November 23, 1994 (Volume 59, Number 225)
- [Microbial Pesticides: Experimental Use Permits and Notifications](#)  
Federal Register: September 1, 1994 (Volume 59, Number 169)
- [Statement of Policy; Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act \(DELETE??\)](#)  
Federal Register: June 26, 1986 (Volume 51, Number 123)

### **Regulations under TSCA**

40 CFR Part 725 - Reporting Requirements and Review Processes for Microorganisms

- Microbial Products of Biotechnology; Final Regulation Under the Toxic Substances Control Act  
Federal Register: April 11, 1997 (Volume 62, Number 70)
- 

### **FDA**

#### **LAWS**

- Federal Food, Drug, and Cosmetic Act (FFDCA) - 21 USC 9

#### **REGULATIONS**

- Statement of Policy: Foods Derived from New Plant Varieties  
Federal Register: May 29, 1992 (Volume 57, Number 104)

### **BIOTECHNOLOGY REGULATORY HISTORY**

- Cronological History of Biotechnology Regulation